K120872

APR 20 2012

8.0 Revised 510(K) SUMMARY
Date Prepared: April 10, 2012

8.1 SUMMARY OF SAFETY AND EFFECTIVENESS

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8.2 Trade/Proprietary Name: asante conset™ and asante comfort™ Subcutaneous Infusion Sets for use with Asante Pearl™ infusion Pumps

8.3 Common/Usual Name: Subcutaneous Infusion Set

8.4 Classification Name: Intravascular Administration Set

8.5 Predicate Devices

The asante comfort™ infusion sets for use with the Asante Pearl™ Pump are substantially equivalent to the current Unomedical Comfort™(K972135) and asante conset™ infusion sets for use with the Asante Pearl™ Pump are substantially equivalent to the Unomedical Inset™ (K032854) infusion sets.

8.6 General Description

8.6.1 Asante comfort™

The asante comfort™ Subcutaneous Infusion Sets for use with the Asante Pearl™ pump and the currently marketed Comfort™ Subcutaneous Infusion Sets are both sterile, non-pyrogenic, single use subcutaneous infusion sets. For the connection to the infusion set, the current Comfort™ sets have a standard female luer connector compatible with many commercially available infusion devices while the new asante comfort™ sets have the unique connector/adapter only compatible with the Asante Insulin Infusion Pump cleared as part of the Asante Pearl™ Diabetes Management System 510(k), file number K100567. This connector/adapter is provided to Unomedical as a finished, tested component by Asante Solutions, the manufacturer of the Asante Pump, and is bonded,us ing the same adhesive, to the pump end of a standard Comfort™ infusion set in lieu of the female luer by Unomedical. The remainder of the set, including all fluid contact materials, sterile packaging, and the manufacturing and sterilization process are unchanged. The method of use of the devices is the same as for the unmodified devices including attaching the connector end of the set to the pump per the pump manufacturers' instructions and the use of the pump with the Comfort™ Subcutaneous Infusion Sets were included as part of the Asante 510(k) file.

8.6.2 Asante conset™

The asante conset™ Subcutaneous Infusion Sets for use with the Asante Pearl™ pump and the current Inset™ Subcutaneous infusion Sets are both sterile, non-pyrogenic, single use subcutaneous infusion sets with an integrated spring-powered catheter insertion device. For the connection to the infusion set, the current Inset™ infusion sets have a standard luer connector compatible with commercially available infusion devices while the new Asante Conset™ sets have a unique connector/adapter compatible with the Asante Pearl™ Infusion Pump cleared as part of the Asante Pearl™ Diabetes Management System 510(k), file number K100567. This part is provided to Unomedical as a finished, tested component by Asante Solutions, the manufacturer of the Asante Pump, and is bonded, using the same adhesive, to the pump end of a standard Inset™ infusion set in lieu of the female luer by Unomedical. The remainder of the set, including all fluid contact materials, sterile packaging, and the manufacturing and sterilization process are unchanged. The method of use of the devices is the same as for the unmodified devices including attaching the connector end of the set to the pump per the pump manufacturers' instructions and the use of the pump with the Inset™ Subcutaneous Infusion Sets were included as part of the Asante 510(k) file.

8.7 Intended Use

8.7.1 Indication for Use

These infusion sets are indicated for the subcutaneous infusion of medication from an external Infusion Pump.

8.7.2 Intended use

These infusion sets are intended to be used only with the Asante Pearl™ Insulin Infusion Pump.

8.8 Technological Characteristics

The asante comfort™ and asante conset™ Subcutaneous Infusion Sets have all of the same technological characteristics as the Unomedical Comfort™ and Unomedical Inset™ Infusion Sets except that a proprietary connector, uniquely compatible with the Asante Pearl™ Insulin Infusion Pump has been substituted for the female luer connector on the pump end of the set.

8.9 Performance Data

The following verification testing was performed on the modified sets:

- 8.9.1 Flow (Occlusion) test
  - 8.9.1.1 asante comfort™ - minimum 40 mL/min at 1 bar pressure
  - 8.9.1.2 asante conset™ - minimum 80 mL/min at 1 bar pressure
- 8.9.2 Leak test
  - 8.9.2.1 No Leaks at 0.56 bar pressure for 30 seconds
- 8.9.3 Pull test
  - 8.9.3.1 Tubing to Asante Adapter – min 15 N

8.10 Conclusion

Unomedical A/S assessed the sterilization cycle, material biocompatibility, and connector function, flow, leak and pull test results to conclude that the new product lines are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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APR 2 0 2012

Re: K120872
Trade/Device Name: Asante Conset™ and Asante Comfort™ Subcutaneous Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 9, 2012
Received: March 22, 2012

Dear Mr. Lindskog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Asante Conset™ and Asante Comfort™ Subcutaneous Infusion Sets "for" the Asante Pearl Insulin Infusion Pump

Indications for Use: These infusion sets are indicated for the subcutaneous infusion of medication from an external Infusion Pump.

Prescription Use ✓ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/19/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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